



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,005	11/20/2001	Eleanor L. Schuler	0607-1006	7962

7590 05/23/2006
Francis Law Group
1942 Embarcadero
Oakland, CA 94606

EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
----------	--------------

3735

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.	Applicant(s)	
	10/000,005	SCHULER ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) Charles A. Marmor, II. (3)_____.

(2) Ralph C. Francis. (4)_____.

Date of Interview: 16 May 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: 1,6,16 and 22.

Identification of prior art discussed: U.S. Patent Nos. 6,171,239 (Humphrey); 4,852,573 (Kennedy); 6,937,903 (Schuler et al); and 6,775,573 (Schuler et al).


Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Charles A. Marmor, II
SPE, Art Unit 3735
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant faxed the attached proposed claim amendments and Declarations under Rule 1.132 for purposes of discussion only. The Examiner indicated that the combination of the proposed amendments and 132 Declarations appeared to obviate the outstanding rejections to Humphrey and Kennedy after a cursory review. The Examiner further indicated that potential obviousness-type double patenting problems exist in at least claim 6 with respect to both of the aforementioned patents to Schuler et al. Finally, the Examiner indicated that the search would have to be updated at least with respect to the proposed amendments to claims 16 and 22 upon entry thereof, which would be broadened to remove the storing step. Applicant indicated that an Request for Continued Examination would likely follow.

Application S/N: 10/000,005
Attorney Docket No.: 0607-1006

Proposed Claim Amendments

Claim 1. (Currently amended) A method for modulating body organ functioning, comprising the steps of:

collecting a plurality of waveforms that are generated in a body and carried by neurons in the body, said plurality of waveforms being operative in the regulation of a plurality of functions of at least one body organ;

storing said collected plurality of waveforms in a storage medium, said step of storing said collected plurality of waveforms including storing said collected plurality of waveforms according to said functions regulated by said collected plurality of waveforms; and

transmitting at least one of said collected plurality of waveforms to a said body organ to regulate organ function, said transmitted waveform signal substantially corresponding to at least one waveform signal that is naturally generated in the body.

Claims 2 -5. (Canceled)

Claim 6. (Currently amended) An apparatus for modulating body organ functioning, comprising:

a source of collected waveforms that are ~~representative of waveforms naturally generated within~~ in a body, said collected waveforms being operative in the regulation of a plurality of functions of at least a first body organ, said source including storage areas adapted to store said collected plurality of waveforms according to said functions regulated by said collected plurality of waveforms;

means for selecting at least a first waveform from said collected plurality of waveforms, said first waveform being operative to regulate said first body organ; and

means adapted to be in communication with the body for broadcasting said first waveform to said first body organ to ~~stimulate or~~ regulate organ function.

Claims 7- 9. (Canceled)

Application S/N: 10/000,005
Attorney Docket No.: 0607-1006

Claim 10. (Previously presented) The apparatus of claim 6, further including means for collecting said collected plurality of waveforms from the body and transmitting said collected plurality of waveforms to said source.

Claim 11. (Previously presented) The apparatus of claim 10, wherein said collecting means comprises a sensor adapted to communicate with the body.

Claims 12-14. (Canceled)

Claim 15. (Previously presented) The apparatus of claim 6, wherein said broadcasting means comprises a body electrode.

Claim 16. (Currently amended) A method for modulating body organ functioning, comprising the steps of:

collecting waveform signals that are ~~representative of waveform signals naturally occurring within~~ generated in a body and that are carried by neurons in the body, said waveform signals being operative in the regulation of body organ functioning; and

transmitting at least one of said collected plurality of waveform signals to a first body organ to regulate organ function, said transmitted waveform signal substantially corresponding to at least one waveform signal that is naturally generated in the body.

Claims 17-21. (Canceled)

Claim 22. (Currently amended) A method for regulating body organ functioning in a body having a nervous system, comprising the steps of:

collecting a plurality of waveforms generated in the body and carried by neurons in the body, said waveforms being operative in the regulation of ~~body organ functioning~~ a plurality of functions of at least one body organ; and

transmitting at least one of said collected plurality of waveforms to the nervous system to regulate the function of ~~[[a]] said body organ~~, said transmitted waveform signal substantially corresponding to at least one waveform signal that is naturally generated in the body.

Proposed Amendment
For Purposes of Discussion Only

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: SCHULER, et al.)
)
 FOR: Method to Record, Store and Broadcast)
 Specific Brain Waveforms to Modulate)
 Body Organ Functioning)
)
 SERIAL NO: 10/000,005)
)
 FILED: November 20, 2001)
)
 ART UNIT NO: 3736)
)
 EXAMINER: Charles A. Marmor, II)
)
 DOCKET NO: 0607-1006)

DECLARATION -- UNDER RULE 1.132

I, Dr. Robert T. Stone, declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that theses statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1. I received a Bachelor of Science Degree in Electrical Engineering (BSEE) from Virginia Polytechnic Institute and State University in 1977; a Master of Science Degree in Electrical Engineering (MSE) from Virginia Polytechnic Institute and State University in 1979; and a Doctorate Degree (PhD) in Electrical Engineering from Stanford University in 1981.

2. I have over thirty (30) years of academic and industry experience in the area of physiological systems, including the analysis and transmission of neuro-electrical coded signals that regulate body functions, and in the field of medical systems and instrumentation, including devices and methods for acquiring and transmitting electrical signals to a subject.

3. I was formerly Vice President of Research and Development, Chief Technical Officer, of Natus Medical, Inc. and am currently Chief Operating Officer, Chief Technical Officer of MedTech Development, LLC, a research and development group with primary emphasis on the medical devices and systems.

4. I am also a named inventor in over twenty (20) issued U.S. Patents and several pending U.S. Patent Applications in the medical field.

5. I am very familiar with the above-referenced patent application, and U.S. Pat. Nos. 6,171,239 to Humphrey and 4,852,573 to Kennedy. I am also familiar with most of Assignee, Science Medicus, Inc.'s, issued patents and pending applications directed to regulation of body organs and systems via neuro-electrical coded signals, including Application No. 11/185,587, entitled "Method and System to Control Skeletal Muscles by Means of Neuro-Electrical Coded Signals", and significant prior art relating to method and systems for regulating body organs via electrical signals.

6. The above referenced application provides clear teaching of collecting a plurality of waveform signals that are generated in the body, the waveform signals being operative in the regulation of a plurality of functions of at least one body organ, and transmitting one of the collected waveform signals to the body to regulate the function of the body organ. A key feature and, hence, advantage of the invention is that the transmitted waveform signal substantially corresponds to the collected waveform signal, i.e. is not subjected to extensive processing and, hence, modification. The transmitted waveform signal is thus substantially similar in form and function to a naturally generated waveform signal.

7. Neither the Humphrey, nor Kennedy reference teaches or suggests transmitting a waveform signal to an organ in the body that is "substantially" similar in form and function to a waveform signal that is naturally generated in the body (and collected therefrom).

8. In Humphrey, the collected waveform signals are subjected to considerable, multi-step processing and, hence, modification to "exteriorize" the signals for transmission. In my opinion, the modified or "exteriorized" signals are substantially different in form and function from waveform signals that are naturally generated in the

*Proposed Declaration
For Purposes of Discussion Only*

body. The "exteriorized" signals thus would not correspond to waveform signals that are naturally generated in the body.

9. The significant differences between the exteriorized signals in Humphrey and naturally generated waveform signals can be readily seen by comparing Figs. 9A -- 9E in Humphrey, which are exteriorized signals resulting from processing signals recorded from the arm area of the sensorimotor cortex of a mammal to Figs. 1A -- 1D (shown in Co-Pending Application No. 11/185,587 and attached in Appendix A), which are illustrations of naturally generated waveform signals that were captured from a body and operative in the control of the skeletal muscles of the arm, forearm, hand and fingers.

Executed this 17th day of May, 2006 in Los Altos, CA

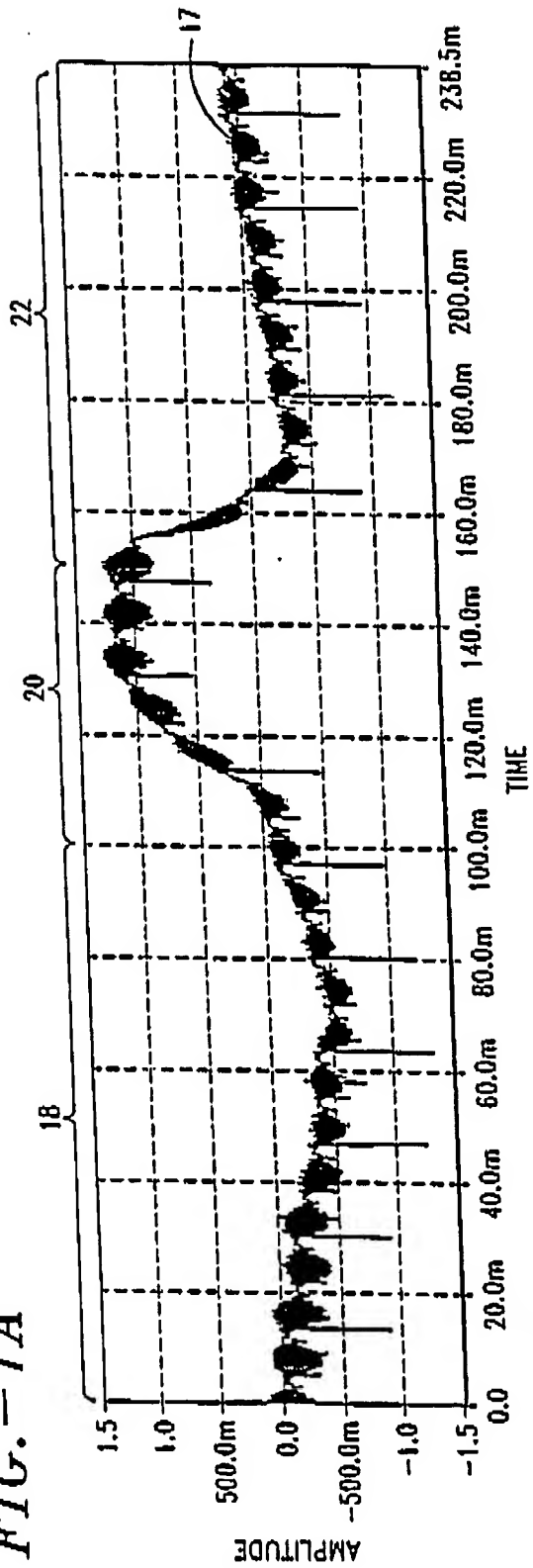
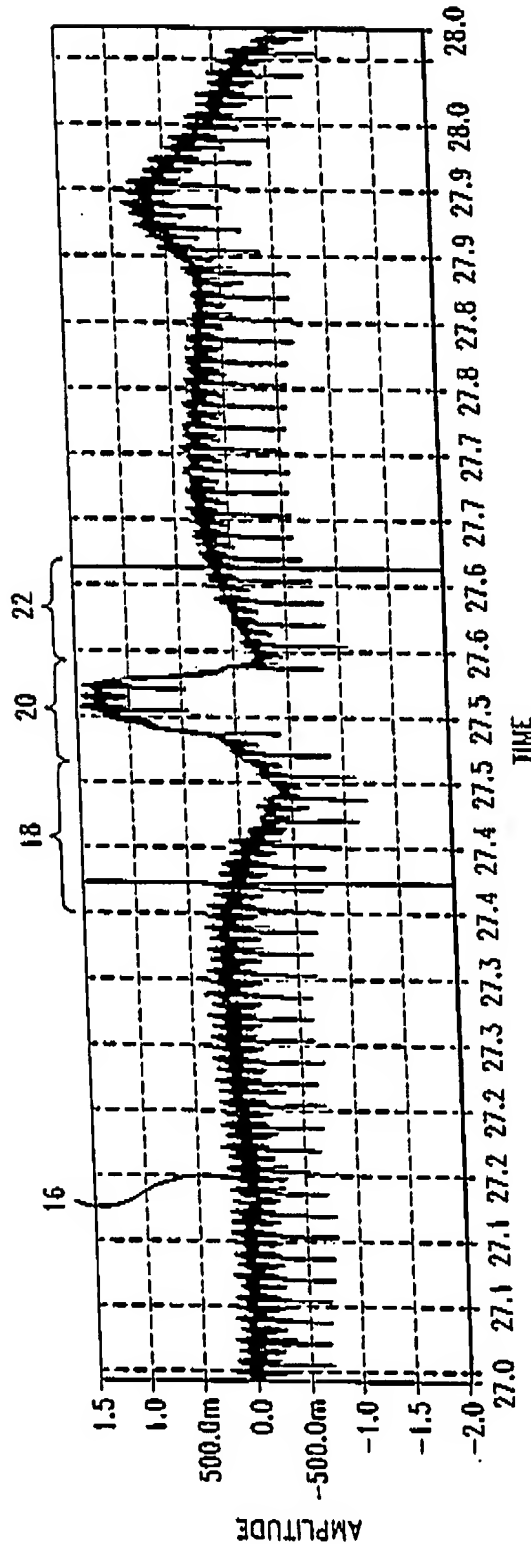


Dr. Robert T. Stone

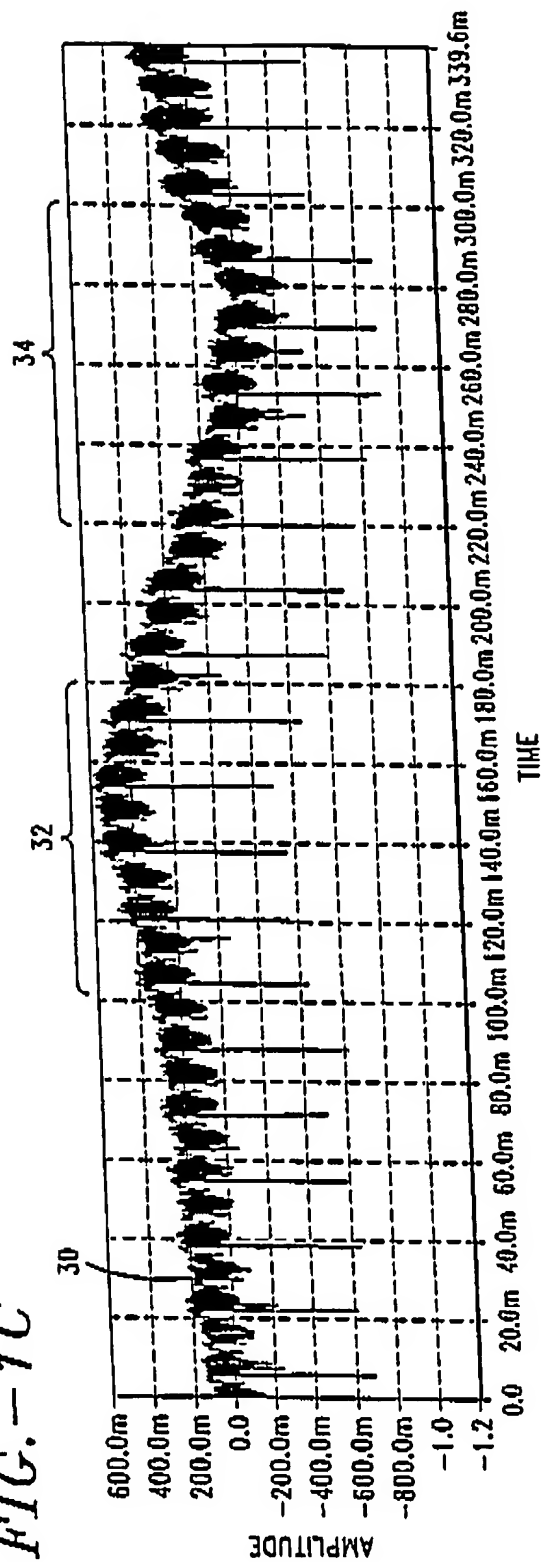
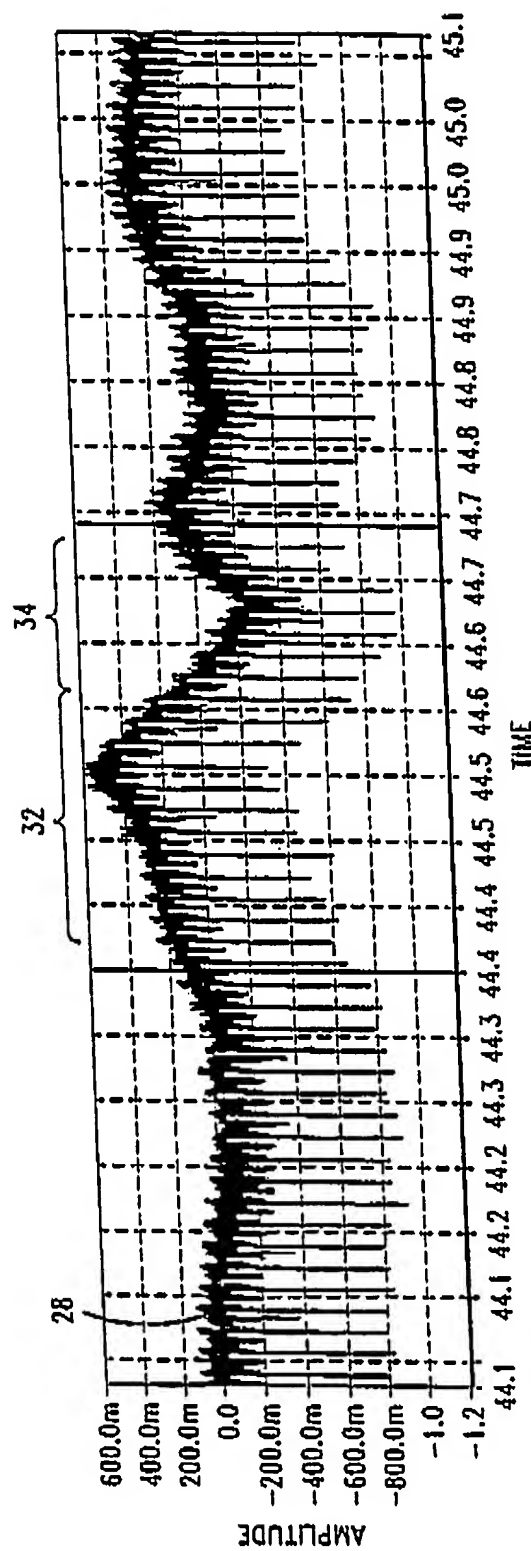
Proposed Declaration
For Purposes of Discussion Only

Appendix A

1/13



2/13



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: SCHULER, et al.
FOR: Method to Record, Store and Broadcast
Specific Brain Waveforms to Modulate
Body Organ Functioning

SERIAL NO: 10/000,005

FILED: November 20, 2001

ART UNIT NO: 3736

EXAMINER: Charles A. Marmor, II

DOCKET NO: 0607-1006

DECLARATION – UNDER RULE 1.132

I, Dr. Dennis Vik, declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

1. I received a Bachelor of Arts Degree in Biology and Chemistry (BA) from Washington University in St. Louis, Missouri in 1979; and a Doctorate Degree (PhD) in Immunology from Harvard University in 1986.

2. I have over 16 years of academic and industry experience in the area of physiological systems, including microbiology, immunology, genetics, cancer biology, and neuroscience, including the analysis and transmission of neuro-electrical coded signals that regulate body functions, and in the field of medical systems and instrumentation, including devices and methods for acquiring and transmitting electrical signals to a subject.

3. I was formerly Chief Science Officer at Protalex, Inc., and Assistant Professor at the University of New Mexico School of Medicine. I am currently Senior Research Scientist at Science Medicus, Inc..

4. I am also a named inventor in several pending U.S. Patent Applications in the medical field.

5. I am very familiar with the above-referenced patent application, and U.S. Pat. Nos. 6,171,239 to Humphrey and 4,852,573 to Kennedy. I am also familiar with all of Assignee, Science Medicus, Inc.'s, issued patents and pending applications directed to regulation of body organs and systems via neuro-electrical coded signals, including Application No. 11/185,587, entitled "Method and System to Control Skeletal Muscles by Means of Neuro-Electrical Coded Signals", and significant prior art relating to method and systems for regulating body organs via electrical signals.

6. In my opinion, the above referenced application provides clear teaching of collecting a plurality of waveform signals that are generated in the body, the waveform signals being operative in the regulation of a plurality of functions of at least one body organ, and transmitting one of the collected waveform signals to the body to regulate the function of the body organ. A key feature and, hence, advantage of the invention is that the transmitted waveform signal substantially corresponds to the collected waveform signal, i.e. is not subjected to extensive processing and, hence, modification. The transmitted waveform signal is thus substantially similar in form and function to a naturally generated waveform signal.

7. An additional advantage of the present invention is that it is based on transmission of neuro-electrical signals to specific peripheral nerves; each of which having its own unique electrical pattern.

8. The method disclosed in the Humphrey reference is substantially different from the present (or subject) invention. The method is based on brain mapping of neuron signals for different movements. The method requires the placement of a multi-probe device on the motor control portion of the brain and the recordation of the different neuron firings or electrical spikes. The disclosed brain mapping thus comprises a 3d array or pattern of electrical spikes that occur for different arm/wrist movements.

*Proposed Declaration
For Purposes of Discussion Only*

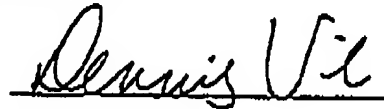
9. To use these patterns to control muscles (by muscle stimulation and not nerve stimulation), one would need to connect to all of the muscles in the arm, wrist, and hand and calibrate the level of electrical current into each of these muscles to achieve the desired amount of movement.

10. It is further submitted that neither the Humphrey reference, nor Kennedy reference teaches or suggests transmitting a waveform signal to an organ in the body that is "substantially" similar in form and function to a waveform signal that is naturally generated in the body (and collected therefrom).

11. The collected waveform signals in Humphrey are subjected to considerable, multi-step processing to "exteriorize" the signals for transmission. In my opinion, the modified or "exteriorized" signals are substantially different in form and function from waveform signals that are naturally generated in the body. The "exteriorized" signals thus would not correspond to waveform signals that are naturally generated in the body.

12. Kennedy merely discloses transmitting "nerve signals to [an] electrode which in turn can be amplified and connected to a control device, which manipulates other devices."

Executed this 11th day of May, 2006 in Albuquerque, NM



Dr. Dennis Vik

Proposed Declaration
For Purposes of Discussion
Only